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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/224,556	12/30/98	DIXIT	V 203442102502

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EXAMINER	
HAYES, R	
ART UNIT	PAPER NUMBER
1647	14

DATE MAILED: 06/19/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/224,556	Dixit
Examiner	**Art Unit**
Robert C. Hayes	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 23, 2001* .

2a) ☒ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *39-42, 44-46, and 49-61* is/are pending in the application.

4a) Of the above, claim(s) *39-42, 44-46, and 58-61* is/are withdrawn from consideration.

5) ☒ Claim(s) *51* is/are allowed.

6) ☒ Claim(s) *49, 50, and 52-57* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *39-42, 44-46, and 49-61* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *12s*
18) ☐ Interview Summary (PTO-413) Paper No(s). _____
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Response to Amendment

1. The amendments filed 2/23/01 and 4/02/01 have been entered.

2. Newly submitted claims 59-61 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Because of the recitation of "pharmaceutically acceptable vector", claim 59-61 are directed toward gene therapy (i.e., see page 16 of the specification), Class 514, subclass 44, which was not previously elected.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 59-61 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. The objection of claims 52-53 & 55-56 under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only, is withdrawn due to the amendment of the claims.

4. The rejection of claims 38 & 56 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter, is withdrawn due to the cancellation or amendment of the claims.

5. The Katz Declaration under 37 CFR 1.132 filed 2/23/01 is sufficient to overcome the rejection of claims 35-38, 43, 47-53 & 55-57 under 35 U.S.C. 102(a) as being anticipated by Hu et al. (IDS REF #20).

6. The Declaration filed on 4/02/01 under 37 CFR 1.131 is sufficient to overcome the rejection of claims 35-38, 43, 47-53 & 55-57 under 35 U.S.C. 102(a) as being anticipated by Sato et al. (IDS REF #32), Mosialos et al. (IDS REF #26), or Cheng et al. (IDS REF #13).

7. Claim 51 is allowed.

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Applicants' arguments filed 2/23/01 have been considered but are not found persuasive.

10. Claim 54 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons made of record in Paper #10, and as follows.

In contrast to Applicants' assertions on page 4 of the response, no proper antecedent basis nor conception in context of that described within the specification at the time of filing the instant invention remains apparent for the recitation, "wherein the carrier is a solid support", as it relates to *compositions of "nucleic acids"*. As previously made of record, page 23 of the specification is directed toward compositions of "any of the above mentioned ***proteins***, [protein] *muteins, **polypeptides** or fragments **thereof***"[emphasis added]; thereby, still constituting new matter. In addition, Applicants' arguments related to use of nucleic acids as probes is moot because no "compositions of probes" are contemplated. Moreover, page 9 is directed toward "CD40bp... bound to a solid phase carrier", which is not equivalent to a *nucleic acid probe* "compositions" being "bound to a solid phase carrier". Nor are any "nucleic acid compositions", or nucleic acids alone, contemplated on page 36 or in Figures 3D-3E, as being "*attached*" thereto, in contrast to Applicants' assertions; thereby, still constituting new matter. Therefore , Applicants' arguments are not persuasive.

11. Claims 49-50 & 52-57 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As previously made of record, in that the claims recite "comprising amino acids 297 to 567", which does not limit the claims to only SEQ ID NO:2, one skilled in the art cannot

reasonably visualize or predict what critical nucleic acid residues would structurally characterize the genus of nucleic acids encoding the genus of CD40 binding proteins "comprising amino acids 297 to 567, as claimed, because it is unknown and not described what structurally constitutes any different nucleic acids encoding CD40bp protein fragments (i.e., "*comprising* amino acids 297 to 567"), or nucleic acids encoding CD40bp from any different species, as still encompassed by claim 49, or any nucleotide sequence that encompasses unknown and undescribed promoter sequences, 5'- or 3'-flanking or enhancer regions, introns, allelic variants, or other sequences "comprising" any CD40 related nucleic acid sequence fragment; thereby, not meeting the written description requirement under 35 U.S.C. 112, first paragraph.

Analogous to the situation decided in *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993), which held that "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself". In addition, *Fiddes v. Baird*, 30 USPQ2d 1481, 1483 (1993) then held that claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class, in which the specification had provided an adequate description of only the bovine sequence. Similarly, only the single species of encoded human CD40bp of SEQ ID NO:2, and its corresponding DNA of SEQ ID NO:1, has been described in the instant specification. Accordingly,

"One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what

the gene does, rather than what it is". *Univ. California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997).

Applicant is directed toward the Revised Interim Utility and Written Description Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999.

12. Claims 49-50 & 52-57 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for the nucleic acid comprising SEQ ID NO:1, or a nucleic acid encoding the human CD40 binding protein (CD40bp) of SEQ ID NO 2, does not reasonably provide enablement for nucleic acid fragments encoding CD40 bp polypeptides that are functionally uncharacterized. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons made of record in Paper #10, and as follows.

Applicants argue on pages 5-6 of the response, that "the essential amino acids necessary to maintain the function of CD40bp polypeptides... [are] identified... [on] pages 37, line 10 through page 38, line 10", that "Applicant has also provided, in one embodiment, the full amino acid sequence for CD40bp", that there is "utility of this invention as a hybridization probe", and cites *Hybritech v. Monoclonal Antibodies* and *In re Wands.* In contrast to Applicants' assertions, the rejected claims are not limited to "the full amino acid sequence for CD40bp [of SEQ ID NO:2]". Nor is this rejection a utility rejection. Nor do pages 37-38 list what sequences (i.e., by SEQ ID

NO) that constitute any "essential amino acids necessary to maintain the function of CD40bp polypeptides". Nor is such functional and assayable characteristics recited in any of the rejected claims. Therefore, the claims remain not enabled, consistent with the teachings of Rudinger previously made of record, which is further consistent with that held by the courts in *In re Wands,* for the reasons made of record. Thus, the limited guidance provided by the instant specification would prevent the skilled artisan from knowing how to make and use Applicants' invention, as claimed, without requiring undue experimentation to determine such, for the reasons made of record in Paper #10.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
June 18, 2001

GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
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